

09-26-05

PTO/SB/21 (02-04)

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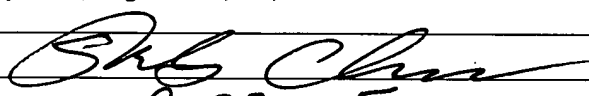
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<b>TRANSMITTAL FORM</b> (to be used for all correspondence after initial filing)	Application Number	10/613,222	
	Filing Date	July 3, 2003	
	First Named Inventor	Joseph Rubinfeld	
	Art Unit	1642	
	Examiner Name	Not yet assigned	
Total Number of Pages in This Submission		Attorney Docket Number	12636-330.201

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
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<input type="checkbox"/> Response to Missing Parts/Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

**SIGNATURE OF APPLICANT, ATTORNEY OR AGENT**

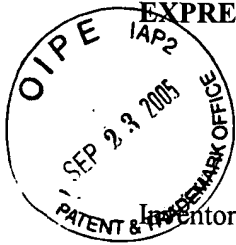
Firm or Individual name	Shirley Chen, Reg. No. 44,608, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	9-23-05

**Express Mail Date: September 23, 2005**

**Express Mail Label No.: EV518897397US**

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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EXPRESS MAIL LABEL NO.: EV 518897397 US

PATENT  
Attorney Docket No. 12636-330.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Joseph RUBINFELD, et al.

Serial Number: 10/613,222

Filing Date: July 3, 2003

Title: RESTORING CANCER-SUPPRESSING  
FUNCTIONS TO NEOPLASTIC CELLS  
THROUGH DNA HYPOMETHYLATION

Group Art Unit: 1642

Examiner: Not yet assigned

CONFIRMATION NO: 7039

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.97**

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08A. A copy of each listed publication is being submitted, if required, pursuant to 37 C.F.R. §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☒ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- ☐ (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;  
-- OR --
- ☒ (3) It is being filed before the mailing date of the first Office Action on the merits;  
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

- ☐ a certification as specified in §1.97(e) provided concurrently herewith;  
-- OR --
- ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

☐ 37 CFR §1.97(e). A certification signed by an Attorney of Record is provided herewith as required under 37 CFR §§1.97(b) and (c).

☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

- ☐ Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.  
-- OR --
- ☐ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.  
-- AND/OR --
- ☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08A are enclosed in accordance with 37 CFR §1.98(a)(2).

-- AND/OR --

- ☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).
- ☐ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation of the non-English language reference(s) is provided herewith.
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.12636-330.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: \_\_\_\_\_

Sept. 23. 2005

650 Page Mill Road  
Palo Alto, CA 94304-1050  
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By: \_\_\_\_\_



Shirley Chen, Reg. No. 44,608

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Sheet	1	of	1	Application Number	10/613,222
				Filing Date	07/03/2003
				First Named Inventor	Joseph RUBINFELD
				Art Unit	1642
				Examiner Name	Not yet assigned
				Attorney Docket Number	12636-330.201

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		MOMPARLER, RICHARD L., et al., "Clinical Trial on 5-AZA-2'-Deoxycytidine in Patients with Acute Leukemia," <i>Pharmac. Ther.</i> (1985) Vol. 30: pp. 277-286	
		PETTI, MARIA CONCETTA, et al., "Pilot Study of 5-Aza-2'-Deoxycytidine (Decitabine) in the Treatment of Poor Prognosis Acute Myelogenous Leukemia Patients: Preliminary Results," <i>Leukemia</i> (1993) Vol. 7, Suppl. Monograph 1: pp. 36-41	
		RICHEL, D.L., et al., "The antileukaemic activity of 5-Aza-2 deoxycytidine (Aza-dC) in patients with relapsed and resistant leukaemia," <i>Br. J. Cancer</i> (1991) 64:144-148	
		RIVARD, GEORGES F., et al., "Phase I Study on 5-AZA-2'-Deoxycytidine in Children with Acute Leukemia," <i>Leukemia Research</i> (1981) Vol. 5 No. 6: pp. 453-462	
		SCHWARTSMANN, G., et al., "Decitabine (5-AZA-2'-deoxycytidine; DAC) plus daunorubicin as a first line treatment in patients with acute myeloid leukemia: preliminary observations," <i>Leukemia</i> (March 1997) Vol. 11, Suppl. 1: S28-S31	
		WIJERMANS, P., et al., "Low-Dose 5-Aza-2'-Deoxycytidine, a DNA Hypomethylating Agent, for the Treatment of High-Risk Myelodysplastic Syndrome: A Multicenter Phase II Study in Elderly Patients," <i>Journal of Clinical Oncology</i> (March 2000) Vol. 18, No. 5: pp. 956-962	
		WIJERMANS, PW, et al., "Continuous infusion of low-dose 5-Aza-2'-deoxycytidine in elderly patients with high-risk myelodysplastic syndrome," <i>Leukemia</i> (March 1997) Vol. 11, Suppl. 1: S19-S23	

Examiner signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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